IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARY HOVEY,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-18900

COOK INCORPORATED, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motions *in Limine*)

Pending before the court are the following motions *in limine* brought by the plaintiff: Motion *in Limine* No. 1 – Evidence Relating to the United States Food and Drug Administration ("FDA") [Docket 65]; and Motion *in Limine* No. 2 – Evidence Relating to Testing Conducted on Products Not at Issue in this MDL [Docket 66]. Also pending before the court are the defendants' Initial Motions *in Limine* (Nos. 1–17) [Docket 70].

For the reasons discussed below, the plaintiff's Motion *in Limine* No. 1 [Docket 65] is **GRANTED**, and the plaintiff's Motion *in Limine* No. 2 [Docket 66] is **DENIED**. The defendants' Initial Motions *in Limine* (Nos. 1–17) [Docket 70] are **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. More specifically: (1) Motion to Preclude Any Evidence or Argument Concerning Cook's Post-Implant Conduct is **GRANTED in part** and **DENIED in part**; (2) Motion to Preclude Any Evidence or Argument Concerning the MAUDE Database and Medical Device Reports is **DENIED**; (3) Motion for Bifurcation of Plaintiffs' Punitive Damages Claim and to Preclude Evidence of Cook's Financial Status Until Punitive Damages Phase of Trial is **GRANTED**; (4) Motion to Preclude Evidence and Argument

Concerning Fraud Against the FDA or Purported FDA Violations is **GRANTED**; (5) Motion to Preclude Any Evidence or Argument Concerning Cook's Decision to Stop Selling the Biodesign Products at Issue, Including Any Suggestion that the Products Were Recalled is **GRANTED**; (6) Motion to Preclude Any Evidence or Argument Regarding Liability Insurance is **GRANTED**; (7) Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Involving SIS Pelvic Repair Products is **GRANTED**; (8) Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Unrelated to Cook's SIS Urethral Sling and Pelvic Graft Products is **GRANTED**; (9) Motion to Preclude Any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Urethral Sling and Pelvic Graft Products is **GRANTED**; (10) Motion to Preclude Any Evidence or Argument Concerning FDA Investigations, FDA Corporate Warnings, or Other FDA Communications Related to Cook Products Not at Issue in this Litigation is **GRANTED**; (11) Motion to Preclude Any Evidence or Argument Concerning the Parties' Conduct During Litigation is **GRANTED in part** and **DENIED in part**; (12) Motion to Preclude Any Evidence or Argument that Cook Owed a Duty to Warn Plaintiffs Directly **GRANTED**; (13) Motion to Preclude Plaintiffs from Referring to Cook's Products at Issue as "Mesh," "Surgical Mesh," "Pelvic Mesh," or "Transvaginal Mesh" is **RESERVED**; (14) Motion to Preclude Plaintiffs from Introducing Any Evidence or Argument Concerning the FDA's October 20, 2008 and July 13, 2011 Public Health Notifications is **GRANTED**; (15) Motion to Preclude Any Evidence or Argument Concerning Cook Entities Not Named is **DENIED**; (16) Motion to Preclude Evidence Concerning Cook's Vaginal Erosion Repair Graft is **GRANTED**; and (17) Motion to Preclude Evidence Concerning Tom

Worthington's May 17, 2006 Letter to Bobby Batemen Which Was the Subject of Significant Questioning During Worthington's February 26, 2014 Deposition is **DENIED**.

I. Background

This case against Cook Incorporated, Cook Biotech, Inc., and Cook Medical, Inc. (collectively "Cook") resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").[1] In the seven MDLs, there are more than 70,000 cases currently pending, approximately 350 of which are in the Cook MDL, MDL 2440. In this particular case, the plaintiff, Mary Hovey, was surgically implanted with the Stratasis Urethral Sling ("Stratasis"), a pelvic repair product made of SIS material that Cook manufactures to treat SUI. (Compl. [Docket 1] ¶ 24). Ms. Hovey received her surgery at Christus Spohn Hospital Shoreline in Corpus Christi, Texas on May 15, 2003. (*Id.*). She now claims that as a result of the implantation of the Stratasis, she has "suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life." (*Id.* ¶ 1). Ms. Hovey advances the following causes of action against Cook: failure to warn under the Product Liability Act, strict liability, negligence, negligent misrepresentation, negligent infliction of emotional distress, breach of express warranty, breach of implied warranty, violation of consumer protection laws, gross negligence, unjust enrichment, and punitive damages. (*Id.* ¶¶ 41–130). The instant motions *in limine* involve the parties' efforts to exclude or limit certain evidence, arguments, and testimony at trial.

[1] In the interest of clarity, I note that the pelvic repair products manufactured by Cook do not contain polypropylene mesh like most of the products at issue in the other MDLs before this court. Rather, Cook manufactures its products using a biologic material made from porcine small intestinal submucosa ("SIS"), (Compl. [Docket 1] ¶ 5), which, in layman's terms, is the tissue from the small intestine of a pig.

II. The Plaintiff's Motions *in Limine*

1. Evidence Relating to the FDA

First, the plaintiff moves to preclude evidence relating to the FDA or the FDA's 510(k) clearance process under Federal Rules of Evidence 401, 402 and 403.[2] As the plaintiff points out, this court has excluded FDA evidence in every MDL trial to date based on these rules. *See, e.g.*, *Cisson v. C. R. Bard, Inc.*, __ F. Supp. 3d __, *4 (S.D. W. Va. 2015), *available at* 2015 WL 566959 (listing cases). I see no reason to depart from this position here.

Rule 401 provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. The plaintiff contends that because the FDA's 510(k) process does not go to whether a product is safe or effective, it has no probative value to the plaintiff's state law tort claims and should therefore be excluded. Once again, I agree. The Supreme Court has held that compliance with 510(k) focuses on "equivalence, not safety," and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety and efficacy." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008) (explaining that the 510(k) process is an "exemption from federal safety review"). If 510(k) does not go to a product's independent safety and efficacy—the "very subjects" of the plaintiff's products liability claims, *id.* at 323—then evidence of Cook's compliance with 510(k) has minimal relevance in this case and should be excluded by the court. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible.").

Even assuming that 510(k) clearance satisfied the relevance standard of Rule 401, I

[2] For a discussion on the 510(k) clearance process, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

nevertheless find that the balancing test set forth in Rule 403 forecloses the admission of FDA evidence. Rule 403 permits exclusion of relevant evidence "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Here, evidence of the FDA regulations—which are not at issue in the case—and Cook's compliance with § 510(k) of the FDCA—which says nothing about the independent safety of the product—could lead to more confusion about the state tort claims than enlightenment. As I explained in *Lewis v. Johnson & Johnson*:

> [a]dmission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value. . . . Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

991 F. Supp. 2d 748, 754–55 (S.D. W. Va. 2014). Introducing 510(k) evidence could also provoke the parties to engage in a time-consuming mini-trial on whether Cook in fact complied with its provisions. Excluding evidence of 510(k) compliance, as well as other FDA evidence, avoids these risks.

Cook's attempts to get around the court's previous holdings on this matter are not persuasive. First, Cook attempts to diminish the controlling law set forth in *Lohr* by pointing to an internal evaluation from the FDA, which expresses the view that modifications to the 510(k) program over time have formed it into a "multifaceted premarket review process" that "provide[s] reasonable assurance of safety and effectiveness." (Cook's Resp. to Pl.'s Mot. *in Limine* No. 1 [Docket 76], at 2 (quoting Ctr. For Device & Radiological Health, *510(k) Working*

Group Preliminary Report and Recommendations 34 (2010))). Given the Supreme Court's clear analysis in *Lohr*, I decline to give this internal evaluation any deference. The FDA cautions that internal reports are "preliminary" and do not reflect any "decisions on specific changes to pursue." Jeffrey Shuren, Director, Ctr. for Devices & Radiological Health, *Foreword: A Message from the Center Director* 5 (2010). Thus, while cognizant of these recommendations, I must defer to the current Code of Federal Regulations and Supreme Court precedent, both of which consistently maintain that 510(k) clearance does not focus on product safety. *See Lohr*, 518 U.S. at 493 (1996) ("[T]he 510(k) process is focused on equivalence, not safety."); 21 C.F.R. § 807.97 (2012) (providing that 510(k) clearance "does not in any way denote official approval of the device" and "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding").[3]

In its next attempt to convince the court of the relevance of FDA compliance, Cook points to the Restatement (Third) of Torts, which provides that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in

[3] Furthermore, the most recent FDA commentary on 510(k) clearance, published after the internal evaluation, indicates concurrence with these authoritative sources. *See generally* FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff* ("Guidance Document") (July 28, 2014), *available at* http://www.fda.gov/downloads/medical devices/deviceregulationandguidance/guidancedocuments/ucm284443.htm (last visited Mar. 19, 2015). Crucially, the Guidance Document distinguishes between the vigorous analysis of product safety conducted under the premarket approval process and the more lax "evidentiary standard" applied in the 510(k) review process. *Id.* at 7. For premarket approval, the medical device must independently demonstrate safety and effectiveness. *Id.* at 6. In contrast, for 510(k) review, the FDA considers safety and effectiveness comparatively, "generally rel[ying], in part, on FDA's prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device." *Id.* at 7. The analysis is predominantly relative, and the FDA does not engage in an independent investigation of the medical device's safety and effectiveness. *Id.* ("FDA generally evaluates differences between the new device and the predicate device to determine their effect on safety and effectiveness."). The language of the Guidance Document therefore confirms this court's conclusion that compliance with 510(k) has little to no relevance in a matter of state tort law that revolves around the objective safety of a product. Likewise, Cook's appeal to the Safe Medical Device Act of 1990, which was enacted years before the Guidance Document, is unpersuasive.

determining whether the product is defective[.]" Restatement (Third) of Torts: Products Liability § 4 (1998). Because the Restatement expressly focuses on compliance with *safety* statutes and regulations, I do not find it applicable. Cook then cites to two cases in which the court held that "compliance with federal regulations is relevant and admissible on the question of defectiveness, but is not necessarily controlling." (Cook's Resp. to Pl.'s Mot. *in Limine* No. 1 [Docket 76], at 3 n.3). These cases carry little persuasive weight in this matter, given that they were decided in 1987, three years before the Supreme Court interpreted 510(k) as focusing on "equivalence, not safety." *Lohr*, 518 U.S. at 478–79.

In sum, even if FDA evidence met the relevance requirements set forth in Rule 401, the substantial risks of misleading the jury and wasting judicial resources by diving into a morass of FDA regulations—none of which relate to the state law claims at issue—weigh heavily in favor of exclusion. For these reasons, FDA evidence, along with evidence of 510(k) compliance, is **EXCLUDED** in its entirety, and the plaintiff's Motion *in Limine* No. 1 [Docket 65] is **GRANTED**.

2. Evidence Relating to Testing Conducted on Products Not at Issue in this MDL

Next, the plaintiff moves to preclude evidence relating to testing that Cook performed on products other than those at issue in this case. The plaintiff contends that evidence of testing performed on SIS products used "in other parts of the human anatomy or to treat conditions other than SUI or POP" is irrelevant and prejudicial. (*Id.* at 1–2). I disagree. All of Cook's products, including the transvaginal slings for treatment of POP and SUI, are made from SIS material. (Cook's Resp. in Opp. to Pl.'s Mot. *in Limine* No. 2 [Docket 78], at 2). And the plaintiff's allegations that Cook's products are defective appear to focus on the characteristics of the SIS

material when used generally as a biologic graft. (*See* Pl. Short Form Compl. [Docket 1], at ¶ 23 (discussing various studies on the use of SIS as a biologic graft—both in the vagina and in the abdomen—in support of its argument that Cook's products are not resistant to infection or inflammation); *see also* Cook's Ex. 2 [Docket 78-2] (demonstrating that more than half of the studies relied upon by the plaintiff concentrate on the broad use of SIS, rather than the narrow use of SIS as a transvaginal sling)). Thus, Cook's testing of SIS material in any respect has probative value in Cook's defense of its product. *See* Fed. R. Evid. 401 (providing that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence").

At this time, I cannot see how this probative value is outweighed by the purported risks of prejudice or confusing the jury. Furthermore, because Cook has provided the plaintiff with "all responsive documents" related to testing on the product at issue, as well as other SIS products, (Cook's Resp. in Opp. to Pl.'s Mot. *in Limine*, No. 2 [Docket 78], at 3), I am not persuaded by the plaintiff's argument that she "lack[s] discovery on such testing." (Pl. Mot. *in Limine* [Docket 66], at 2–3). For these reasons, the plaintiff's Motion *in Limine* No. 2 is **DENIED**.

III. Cook's Motions *in Limine*

1. Motion to Preclude Any Evidence or Argument Concerning Cook's Post-Implant Conduct

Cook moves to preclude any evidence concerning Cook's post-implant conduct, actions by Cook, or actions by the FDA because it is irrelevant and would cause unfair prejudice. Cook also argues that such evidence is inadmissible under Federal Rule of Evidence 407 as a subsequent remedial measure. The plaintiff states that she "will not introduce evidence of (a)

defendants' ultimate removal of products from the market or (b) FDA actions against defendants' products[.]" (Pl.'s Reply to Cook's Initial Mots. *in Limine* (Nos. 1-17) ("Pl.'s Reply") [Docket 74], at 1). Accordingly, Cook's Motion *in Limine* No. 1 is **GRANTED** with regard to those two categories of evidence. With regard to other post-implant conduct by Cook, this issue is better suited for trial as evidence is presented. Furthermore, evidence of subsequent remedial measures that is inadmissible to prove "negligence; culpable conduct; a defect in a product or its design; or a need for warning or instruction," may be admitted "for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." Fed. R. Evid. 407. In other words, the admissibility of such evidence or argument depends on the context and method by which the plaintiff seeks to introduce it. Accordingly, the remainder of Cook's Motion *in Limine* No. 1 is **DENIED**.

2. Motion to Preclude Any Evidence or Argument Concerning the MAUDE Database and Medical Device Reports

Cook moves to preclude evidence concerning the MAUDE database and Medical Device Reports because it is inadmissible hearsay, irrelevant, and would cause unfair prejudice and jury confusion. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Cook's Motion *in Limine* No. 2 is **DENIED**.

3. Motion for Bifurcation of Plaintiffs' Punitive Damages Claim and to Preclude Evidence of Cook's Financial Status Until Punitive Damages Phase of Trial

First, Cook moves to bifurcate the plaintiff's compensatory and punitive damages claims. The plaintiff has "no objection to bifurcation so long as plaintiffs' entitlement to punitive damages is decided in the first phase of trial, with only the amount of punitive damages (if any) to be reserved for the second phase." (Pl.'s Reply [Docket 74], at 5). Accordingly, I **GRANT** Cook's Motion for Bifurcation.

Cook also moves to preclude evidence of Cook's financials from the first phase of trial. Evidence of Cook's financials is certainly relevant as to the amount of punitive damages and therefore relevant to the second phase of the trial. However, I **FIND** the probative value of allowing evidence of Cook's financials during the first phase of trial is substantially outweighed by the danger of confusing the issues or misleading the jury. Fed. R. Evid. 403. Such evidence is more appropriately considered during the second phase of the trial, which, if necessary, would focus on the amount of punitive damages. Accordingly, Cook's Motion *in Limine* No. 3 is **GRANTED**.

4. Motion to Preclude Evidence and Argument Concerning Fraud Against the FDA or Purported FDA Violations

Cook moves to preclude evidence concerning fraud against the FDA or FDA violations because it is inadmissible under *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). Cook also argues that such evidence is unfairly prejudicial and would mislead and confuse the jury. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 4 is **GRANTED**.

5. Motion to Preclude Any Evidence or Argument Concerning Cook's Decision to Stop Selling the Biodesign Products at Issue, Including Any Suggestion that the Products Were Recalled

Cook moves to preclude evidence concerning Cook's decision to stop selling its Biodesign products because it is irrelevant, unfairly prejudicial, and has the potential to mislead the jury and result in undue delay. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 5 is **GRANTED**.

6. Motion to Preclude Any Evidence or Argument Regarding Liability Insurance

Cook moves to preclude evidence concerning Cook's liability insurance because it is irrelevant. Cook also argues that such evidence is inadmissible under Federal Rule of Evidence 411 to prove negligence or wrongdoing. The plaintiff does not intend to offer evidence concerning Cook's liability insurance. Accordingly, Cook's Motion *in Limine* No. 6 is **GRANTED**.

7. Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Involving SIS Pelvic Repair Products

Cook moves to preclude evidence concerning other lawsuits against Cook involving SIS products because it is irrelevant and unfairly prejudicial. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 7 is **GRANTED**.

8. Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Unrelated to Cook's SIS Urethral Sling and Pelvic Graft Products

Cook moves to preclude evidence concerning other lawsuits against Cook involving non-SIS products because it is irrelevant and unfairly prejudicial. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 8 is **GRANTED**.

9. Motion to Preclude Any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Urethral Sling and Pelvic Graft Products

Cook moves to preclude evidence concerning other lawsuits against other manufacturers because it is irrelevant and unfairly prejudicial. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 9 is **GRANTED**.

10. Motion to Preclude Any Evidence or Argument Concerning FDA Investigations, FDA Corporate Warnings, or Other FDA Communications Related to Cook Products Not at Issue in this Litigation

Cook moves to preclude evidence concerning FDA corporate warnings, communications, or investigations related to Cook products not at issue in this case because it is irrelevant and unfairly prejudicial. Cook also argues that such evidence is inadmissible under Federal Rule of Evidence 404. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 10 is **GRANTED**.

11. Motion to Preclude Any Evidence or Argument Concerning the Parties' Conduct During Litigation

Cook moves to preclude evidence of the parties' litigation conduct, including (1) settlement negotiations; (2) Cook's designation of documents as confidential; (3) suggestion that Cook delayed the discovery process; (4) objections made by Cook in responding to discovery; and (5) the court's rulings on issues during discovery. The plaintiff does not contest this motion, with the exception of the fourth category: objections made by Cook in responding to discovery. The plaintiff argues that Cook's motion with regard to this particular conduct is vague and over broad. I agree. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. Accordingly, Cook's

Motion *in Limine* No. 11 is **DENIED** with regard to objections made by Cook in responding to discovery and **GRANTED** with regard to the remaining categories of conduct.

12. Motion to Preclude Any Evidence or Argument that Cook Owed or Breached a Duty to Warn Plaintiffs Directly

Cook moves to preclude evidence that Cook had a duty to warn the plaintiff directly in light of the learned intermediary doctrine. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 12 is **GRANTED**.[4]

13. Motion to Preclude Plaintiffs from Referring to Cook's Products at Issue as "Mesh," "Surgical Mesh," "Pelvic Mesh," or "Transvaginal Mesh"

Cook moves to preclude any reference to Cook SIS products as mesh, surgical mesh, pelvic mesh, or transvaginal mesh because it would be inaccurate, incorrect, and unduly prejudicial. In response, the plaintiff argues that Cook should not be permitted to dictate the terminology that the plaintiff or her experts use. The court **RESERVES** ruling on Cook's Motion *in Limine* No. 13 and will take up this issue at the pretrial conference scheduled for May 13, 2015 at 10:00 AM.

14. Motion to Preclude Plaintiffs from Introducing Any Evidence or Argument Concerning the FDA's October 20, 2008 and July 13, 2011 Public Health Notifications

Cook moves to preclude evidence of two FDA Public Health Notifications because it is unfairly prejudicial. The plaintiff does not contest this motion. Accordingly, Cook's Motion *in Limine* No. 14 is **GRANTED**.

15. Motion to Preclude Any Evidence or Argument Concerning Cook Entities Not Named

[4] I acknowledge the plaintiff's "caveats" and note that this holding is limited to Cook's duty to warn. Whether the plaintiff "should be precluded from showing that defendants' patient information/brochure misstated the risks and benefits of the products" is not an evidentiary issue currently before the court. (Pl.'s Reply [Docket 74], at 11).

Cook moves to preclude any reference to Cook entities or subsidiaries not named in the present action because it is irrelevant and unfairly prejudicial. An evidentiary ruling on this issue depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature. (*See* Pl.'s Reply [Docket 74], at 14 ("However, Cook does not point to any specific examples of evidence that it expects the Plaintiffs to present at trial. Instead, it only gives a cursory description of its corporate structure[.]")). Accordingly, Cook's Motion *in Limine* No. 15 is **DENIED**.

16. Motion to Preclude Evidence Concerning Cook's Vaginal Erosion Repair Graft

Cook moves to preclude evidence concerning Cook's Biodesign Vaginal Erosion Repair Graft ("VERG") because it is irrelevant and unfairly prejudicial. The plaintiff does not intend to offer evidence concerning Cook's VERG. Accordingly, Cook's Motion *in Limine* No. 16 is **GRANTED**.

17. Motion to Preclude Evidence Concerning Tom Worthington's May 17, 2006 Letter to Bobby Bateman Which Was the Subject of Significant Questioning During Worthington's February 26, 2014 Deposition

Cook moves to preclude evidence of or reference to a letter written by Tom Worthington because it is inadmissible under Federal Rule of Evidence 407 as a subsequent remedial measure. As discussed more fully *supra* related to Cook's Motion *in Limine* No. 1, this issue is better suited for trial as evidence is presented. Accordingly, Cook's Motion *in Limine* No. 17 is **DENIED**.

IV. Conclusion

To reiterate: The plaintiff's Motion *in Limine* No. 1 [Docket 65] is **GRANTED**, and the plaintiff's Motion *in Limine* No. 2 [Docket 66] is **DENIED**. The defendants' Initial Motions *in Limine* (Nos. 1–17) [Docket 70] are **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. More specifically: (1) Motion to Preclude Any Evidence or Argument Concerning Cook's Post-Implant Conduct is **GRANTED in part** and **DENIED in part**; (2) Motion to Preclude Any Evidence or Argument Concerning the MAUDE Database and Medical Device Reports is **DENIED**; (3) Motion for Bifurcation of Plaintiffs' Punitive Damages Claim and to Preclude Evidence of Cook's Financial Status Until Punitive Damages Phase of Trial is **GRANTED**; (4) Motion to Preclude Evidence and Argument Concerning Fraud Against the FDA or Purported FDA Violations is **GRANTED**; (5) Motion to Preclude Any Evidence or Argument Concerning Cook's Decision to Stop Selling the Biodesign Products at Issue, Including Any Suggestion that the Products Were Recalled is **GRANTED**; (6) Motion to Preclude Any Evidence or Argument Regarding Liability Insurance is **GRANTED**; (7) Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Involving SIS Pelvic Repair Products is **GRANTED**; (8) Motion to Preclude Any Evidence or Argument Concerning Other Lawsuits Against Cook Unrelated to Cook's SIS Urethral Sling and Pelvic Graft Products is **GRANTED**; (9) Motion to Preclude Any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Urethral Sling and Pelvic Graft Products is **GRANTED**; (10) Motion to Preclude Any Evidence or Argument Concerning FDA Investigations, FDA Corporate Warnings, or Other FDA Communications Related to Cook Products Not at Issue in this Litigation is **GRANTED**; (11) Motion to Preclude Any Evidence or

Argument Concerning the Parties' Conduct During Litigation is **GRANTED in part** and **DENIED in part**; (12) Motion to Preclude Any Evidence or Argument that Cook Owed a Duty to Warn Plaintiffs Directly **GRANTED**; (13) Motion to Preclude Plaintiffs from Referring to Cook's Products at Issue as "Mesh," "Surgical Mesh," "Pelvic Mesh," or "Transvaginal Mesh" is **RESERVED**; (14) Motion to Preclude Plaintiffs from Introducing Any Evidence or Argument Concerning the FDA's October 20, 2008 and July 13, 2011 Public Health Notifications is **GRANTED**; (15) Motion to Preclude Any Evidence or Argument Concerning Cook Entities Not Named is **DENIED**; (16) Motion to Preclude Evidence Concerning Cook's Vaginal Erosion Repair Graft is **GRANTED**; and (17) Motion to Preclude Evidence Concerning Tom Worthington's May 17, 2006 Letter to Bobby Batemen Which Was the Subject of Significant Questioning During Worthington's February 26, 2014 Deposition is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 26, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE